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| 10/511,711 | 04/07/2005 | Niklas Ahlborg | 102672-103 | 6727 |
| 27267 7590 05/20/2008 WIGGIN AND DANA LLP ATTENTION: PATENT DOCKETING ONE CENTURY TOWER, P.O. BOX 1832 NEW HAVEN, CT 06508-1832 | | | EXAMINER GRUN, JAMES LESLIE | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/511,711

Applicant(s)

AHLBORG ET AL.

Examiner

JAMES L. GRUN

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2008.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 15-26, 33, 34 and 41-44 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-9, 15-26, 33, 34 and 41-44 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/808)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

The amendment filed 11 March 2008 is acknowledged and has been entered. Claims 43 and 44 are newly added. Claims 10-14, 27-32, and 35-40 have been cancelled. Claims 1-9, 15-26, 33, 34, and 41-44 remain in the case.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 15-26, 33, 34, and 41-44 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 and claims dependent thereupon, improper Markush language is used to claim the members of the group. The alternatives "selected from...or" or "selected from the group consisting of...and" are acceptable. It is believed --exudate-- was intended. Recitations of "the" result, results, or amount lack antecedent basis.

In claims 22 and 23 it is not clear what in claim 1 is being further limited.

In claims 25 and 26, the relationships of the peptides to the scaffold protein or domains thereof are not clear.

Claim 33 would be clearer if the sample --is obtained from a human--.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

(c) Subject matter developed by another person, which qualifies as prior art only under one or more subsections (e), (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 1-8, 15-26, 33, 34, and 41-44 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of Hansson et al. (Immunotechnol. 4: 237, 1999), Cozzette et al. (US 5,837,446), and Self (US 4,595,655) for reasons of record in the prior rejection of the similar subject matter of these claims.

Applicant's arguments filed 11 March 2008 have been fully considered but they are not deemed to be persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., avoidance of heterophilic antibody interference) are not recited in the rejected claim(s) and the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this regard, applicant urges

that the detection of binding to respiratory syncytial virus (RSV) G protein of a sandwich of anti-RSV monoclonal antibodies and an RSV G protein-binding affibody construct derived from a staphylococcal protein A Z domain/streptococcal protein G albumin binding domain fusion protein library in the Hansson et al. reference merely detected simultaneous binding of the two binders to different epitopes. This is not found persuasive for the reasons of record in view of the teachings of Cozzette et al. and Self and in view of the notoriously old and well known necessary step of determining binding specificity for different epitopes for binders to use in a sandwich assay. Applicant urges that Self does not teach affibodies as the non-antibody receptor which binds a ligand of interest. This is not found persuasive for the reasons of record in view of the teachings of Hansson et al. Notwithstanding applicant's assertions to the contrary, the examiner recognizes that references cannot be arbitrarily combined and that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the common knowledge or common sense generally available to one of ordinary skill in the art. See: *In re Nomiya*, 184 USPQ 607 (CCPA 1975); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); or, *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). However, there is no requirement that the claimed invention or a motivation to make the modification be expressly articulated in any one or all of the references. The test for combining references is what the combination of disclosures, taken as a whole, would suggest to one of ordinary skill in the art. See: *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); or, *In re McLaughlin*, 170 USPQ 209 (CCPA 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. See: *In re*

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Bozek, 163 USPQ 545 (CCPA 1969). A person of ordinary skill in the art, using common knowledge and common sense, is capable of fitting the teachings of multiple references together like pieces of a puzzle, regardless of the specific problem being addressed by the individual references. Any need or problem known at the time of the invention can provide a reason for combining elements of the different references. A person of ordinary skill in the art is also a person of ordinary creativity. In this case, for the reasons of record, ample motivation to combine the references with an extremely reasonable expectation of success have been set forth. Nothing unobvious is seen in the combination of the elements taught by the references with an extremely reasonable expectation of success that selected pairs of binding molecules would perform their known and expected function of binding for capture or reporting in a sandwich detection assay.

Claims 1-8, 15-26, 33, 34, and 41-44 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of Ljungqvist et al. (WO 00/63243) and Yu et al. (US 6,197,526) for reasons of record in the prior rejection of the similar subject matter of these claims. In addition to the teachings set forth in the prior Office action, indirect labeling of antibodies by biotin-avidin bridges is notoriously old, well known, and conventional in the art.

Applicant's arguments filed 11 March 2008 have been fully considered but they are not deemed to be persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re*

Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this regard, applicant urges that Ljungqvist et al. do not teach a sandwich assay for quantification. This is not found persuasive as set forth in the rejection of record in view of the teachings of Yu et al. Moreover, Ljungqvist et al. clearly teach the use of their human factor VIII-binding affibody construct derived from a staphylococcal protein A Z domain/streptococcal protein G albumin binding domain fusion protein library for analysis of human factor VIII (see e.g. page 4) and diagnosis of hemophilia (see e.g. pages 1 and 3). Applicant urges that Yu et al. do not provide experimental data supporting a sandwich assay. This is not found persuasive as set forth in the rejection of record in view of the teachings of Ljungqvist et al. The examiner recognizes that references cannot be arbitrarily combined and that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the common knowledge or common sense generally available to one of ordinary skill in the art. See: *In re Nomiya*, 184 USPQ 607 (CCPA 1975); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); or, *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). However, there is no requirement that the claimed invention or a motivation to make the modification be expressly articulated in any one or all of the references. The test for combining references is what the combination of disclosures, taken as a whole, would suggest to one of ordinary skill in the art. See: *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); or, *In re McLaughlin*, 170 USPQ 209 (CCPA 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. See: *In re Bozek*, 163 USPQ 545 (CCPA 1969). A person of ordinary skill in the art, using common knowledge and common sense, is capable of fitting the

teachings of multiple references together like pieces of a puzzle, regardless of the specific problem being addressed by the individual references. Any need or problem known at the time of the invention can provide a reason for combining elements of the different references. A person of ordinary skill in the art is also a person of ordinary creativity. In this case, for the reasons of record, ample motivation to combine the references with an extremely reasonable expectation of success have been set forth. Nothing unobvious is seen in the combination of the elements taught by the references with an extremely reasonable expectation of success that selected pairs of binding molecules would perform their known and expected function of binding for capture or reporting in a sandwich detection assay.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., avoidance of heterophilic antibody interference) are not recited in the rejected claim(s) and the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Claims 1-9, 15-26, 33, 34, and 41-44 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of Lin et al. (US 2002/0037506), Borrebaeck et al. (US 2001/0053520), and Nygren et al. (Curr. Opin. Struct. Biol. 7: 463, 1997) for reasons of record in the prior rejection of the similar subject matter of these claims.

Applicant's arguments filed 11 March 2008 have been fully considered but they are not deemed to be persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this regard, applicant urges that Lin et al. do not teach other than aptamers. This is not found persuasive for the reasons of record in view of the teachings of Borrebaeck et al. and Nygren et al. Applicant urges that Borrebaeck et al. are concerned only with two dimensional gels. This is not found persuasive for a number of reasons. Firstly the argument is not found persuasive because the reference is not relied upon for its teaching of binding assays, only for the notoriously old and well known concept of the substitution of various anti-ligands in a binding assay. However, the argument is also not found persuasive in view of the teachings of the reference regarding diagnostic assays (see e.g. [0064] - [0067]). The examiner recognizes that references cannot be arbitrarily combined and that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the common knowledge or common sense generally available to one of ordinary skill in the art. See: *In re Nomiya*, 184 USPQ 607 (CCPA 1975); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); or, *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). However, there is no requirement that the claimed invention or a motivation to make the modification be expressly articulated in any one or all of the references. The test for combining references is what the combination of disclosures, taken as a whole, would suggest to one of ordinary skill in the art. See: *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); or, *In re McLaughlin*, 170 USPQ 209 (CCPA

1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. See: *In re Bozek*, 163 USPQ 545 (CCPA 1969). A person of ordinary skill in the art, using common knowledge and common sense, is capable of fitting the teachings of multiple references together like pieces of a puzzle, regardless of the specific problem being addressed by the individual references. Any need or problem known at the time of the invention can provide a reason for combining elements of the different references. A person of ordinary skill in the art is also a person of ordinary creativity. In this case, for the reasons of record, ample motivation to combine the references with an extremely reasonable expectation of success have been set forth. Nothing unobvious is seen in the combination of the elements taught by the references with an extremely reasonable expectation of success that selected pairs of binding molecules would perform their known and expected function of binding for capture or reporting in a sandwich detection assay.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J. L. G./

James L. Grun, Ph.D.
Examiner, Art Unit 1641
May 20, 2008

/Christopher L. Chin/
Primary Examiner, Art Unit 1641